Remarks / Arguments

Claims 27-43 are pending in this application. Claim 44 has been canceled. Claims 27, 28, 30-33, and 38-43 have been amended. No new matter has been added.

General remarks

In the present amendment, the claims have been amended to recite that the biological sensor material is bioluminescent cells with reporter gene constructs. In addition, the claim language has been modified to specify that the biological sensor material is suspended throughout the sheet of diffusion-controlling matrix.

Rejections under §112, first paragraph

Claim 28 was rejected for failing to comply with the description requirement, on grounds that "carrier" should be employed instead of "support". The recommended revision has been made.

Claims 38-43 were rejected for their use of "about". This term has been deleted.

Rejections under §102 in view of Sachs '409

Claims 27-29, 31, 32, 34, 35, and 37 were rejected as being anticipated by Sachs '409.

Sachs discloses a screening process and apparatus for identifying anti-helicobactericidal substances modulating ureI dependent mechanisms of gastric Helicobacter metabolism. Gastric Helicobacter cells are treated with a substance to be tested for modulating ureI dependent mechanisms of gastric Helicobacter metabolism, and gastric Helicobacter acid resistance or sensitivity to ureI is determined.

The screen of the reference employs a cytosensor microphysiometer which provides a perfusion system allowing real time determination of the metabolic activity of small populations of living cells. The machine allows measurement of the rate at which cells acidify or alkalinize the perfusion medium simultaneously in 8 sensor chambers. In these chambers the cells are in close contact via aqueous diffusion with a light addressable potentiometric pH sensor. The

sensor chambers are described as "microvolume flow chambers". The cells are entrapped in the sensor chambers between two microporous membranes using commercially available agarose cell entrapment medium. In operation, the microvolume flow chambers are perfused with an appropriate medium the composition of which may be altered to include substances to be tested as inhibitors. The pH of the medium is monitored before and after contact with the cell-containing sensor chambers.

In the reference system there is no sheet of diffusion-controlling matrix as presently claimed. The cells are instead maintained in the microvolume flow chambers between two microporous membranes. In the reference system there is also no possibility for the material being tested to be in contact with a spacially-discrete area of the sheet of diffusion-controlling matrix. The reference device has no sheet of diffusion-controlling matrix and the material being tested therein is a constituent of the flowing perfusion medium which contacts the microporous membranes between which the cells are maintained. In the reference system there is no means for detecting any spatial distribution of signals produced by a substance brought into contact with a spacially-discrete area of the sheet of diffusion-controlling matrix. As explained above, the reference device does not possess a sheet of diffusion-controlling medium and does not permit the substance being tested to be brought into contact with a spatially-discrete area of a sheet of the diffusion-controlling matrix, so there can be no spatially-discrete signals to be detected. Rather, in the reference system, the detector is a downstream pH sensor, which is only capable of monitoring the pH of the medium after it has passed the microvolume flow chambers. Finally, the reference system does not employ bioluminescent cells with reporter gene constructs as now claimed. Sachs '409 does not anticipate the presently-claimed system.

Rejections under §102 in view of Suzuki '098

Claims 27-36, 41, 42, and 44 were rejected as being anticipated by Suzuki '098.

Suzuki discloses a process and a kit for simultaneous immunoassay of two or more materials in a sample. In the reference system, a "development layer" is produced on a suitable carrier such as a glass plate, and two or more "reagents" (each of which is an antibody or antigen) are fixed at known locations on the development layer. A sample containing materials to be

detected or quantitated is placed on the development layer and moved across the development layer by any of a variety of means, so that the constituents of the sample contact the fixed reagents as the sample moves by them. In the process, the desired constituents (if present) will be bound to respective fixed reagents on the development layer via an antibody-antigen interaction. A suitably-labeled antibody, antigen, or other labeling reagent is brought into contact with each of the fixed reagent areas of the development layer (containing bound analyte material) so that the desired constituents of the original sample become labeled. Detection and quantitation of the labeled analytes is accomplished by appropriate means.

The process and kit of the reference do not employ a biological sensor material suspended throughout a sheet of diffusion-controlling material, as presently claimed. Rather, the reference discloses the use of different "reagents" which are fixed at particular locations on the development layer. Additionally, the reference does not appear to disclose as the biological sensor material bioluminescent cells with reporter gene constructs, as presently claimed. Suzuki does not anticipate the present claims.

Rejections under §103 in view of Sachs '409

Claims 38-43 were rejected as obvious in view of Sachs '409, on grounds that the parameters such as concentration of the biological sensor in the matrix, the optical density of the matrix, and the thickness of the matrix are all "result effective variables which Sachs et al has shown may be altered to achieve optimum results".

Contrary to the examiner's statement, the Sachs reference does not show anything about the mentioned variables in the context of the present invention or otherwise, as it does not disclose a sheet of diffusion-controlling matrix, or the use of reporter gene suspensions as biological sensors. Furthermore, the examiner has not rejected claim 27 as obvious in view of Sachs '409, and the anticipation rejection of claim 27 has been shown to be improper above. Accordingly, claims 38-43 are deemed to be patentable as proper dependent claims referring to a patentable head claim, and the rejection under §103 should be withdrawn.

Rejections under §103 in view of Suzuki '098

Claims 38-40, and 43 were rejected under §103 as obvious in view of Suzuki '098. The examiner has not rejected claim 27 as obvious in view of Suzuki '098, and the anticipation rejection of claim 27 has been shown to improper above. Accordingly, claims 38-40 and 43 are deemed to be patentable as proper dependent claims referring to a patentable head claim, and the rejection under §103 should be withdrawn.

In view of the above amendments and arguments, this application is deemed to be in condition for allowance, and allowance is accordingly requested.

Respectfully submitted,

William F. Gray

Reg. No.: 31018
Phone: (203) 812-2712
Date: 29 June '04

William F. Gray
Bayer Pharmaceuticals Corporation
400 Morgan Lane
West Haven, CT 06516-4175